In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS

Filed: June 26, 2024

MAKAYLAH KELLY,	*	PUBLISHED
Petitioner,	*	No. 21-827V
v.	*	Special Master Dorsey
SECRETARY OF HEALTH AND HUMAN SERVICES,	*	Dismissal; Human Papillomavirus ("HPV") Vaccine; Postural Orthostatic Tachycardia Syndrome ("POTS").
Respondent.	*	

David Charles Richards, Christensen & Jensen, P.C., Salt Lake City, UT, for Petitioner.
Madelyn Weeks, U.S. Department of Justice, Washington, DC, for Respondent.

DECISION[1]

On February 1, 2021, Makaylah Kelly ("Petitioner") filed a petition for compensation under the National Vaccine Injury Compensation Program ("Vaccine Act" or "the Program"), 42 U.S.C. § 300aa-10 et seq. (2018),[2] alleging that she suffered from postural orthostatic

[1] Because this Decision contains a reasoned explanation for the action in this case, the undersigned is required to post it on the United States Court of Federal Claims' website and/or at https://www.govinfo.gov/app/collection/uscourts/national/cofc in accordance with the E-Government Act of 2002. 44 U.S.C. § 3501 note (2018) (Federal Management and Promotion of Electronic Government Services). **This means the Decision will be available to anyone with access to the Internet.** In accordance with Vaccine Rule 18(b), Petitioner has 14 days to identify and move to redact medical or other information, the disclosure of which would constitute an unwarranted invasion of privacy. If, upon review, the undersigned agrees that the identified material fits within this definition, the undersigned will redact such material from public access.

[2] The National Vaccine Injury Compensation Program is set forth in Part 2 of the National Childhood Vaccine Injury Act of 1986, Pub. L. No. 99-660, 100 Stat. 3755, codified as amended, 42 U.S.C. §§ 300aa-10 to -34 (2018) ("Vaccine Act" or "the Act"). All citations in this Decision to individual sections of the Vaccine Act are to 42 U.S.C.A. § 300aa.

tachycardia syndrome ("POTS")[3] as a result of receiving human papillomavirus ("HPV") vaccination on February 1, 2018. Petition at Preamble (ECF No. 1). Respondent argued against compensation, stating the case was "not appropriate for compensation under the terms of the Act." Respondent's Report ("Resp. Rept.") at 1 (ECF No. 32).

After carefully analyzing and weighing the evidence presented in accordance with the applicable legal standards, the undersigned finds Petitioner has failed to provide preponderant evidence that the HPV vaccination caused her to develop POTS. Thus, Petitioner has failed to satisfy her burden of proof under Althen v. Secretary of Health & Human Services, 418 F.3d 1274, 1280 (Fed. Cir. 2005). Accordingly, the petition must be dismissed.

I. PROCEDURAL HISTORY

Petitioner filed her petition, affidavit, and medical records on February 1, 2021. Petition; Petitioner's Exhibits ("Pet. Exs.") 2-4. Respondent filed his Rule 4(c) report, arguing against compensation, on February 7, 2022. Resp. Rept. at 1.

On July 11, 2022, Petitioner filed an expert report from Dr. Mitchell G. Miglis. Pet. Ex. 20. Respondent filed an expert report from Dr. Andrew MacGinnitie on October 11, 2022, and an expert report from Dr. Brian Olshansky on December 23, 2022. Resp. Exs. A, C. Petitioner filed a supplemental expert report from Dr. Miglis on March 20, 2023. Pet. Ex. 52.

At the request of the parties, a Rule 5 conference was held on May 11, 2023. Rule 5 Order dated May 12, 2023 (ECF No. 60). The undersigned explained that there are other similar Vaccine Program cases involving HPV and POTS and generally, special masters have denied entitlement in those cases. Id. at 1. In at least one of those cases, Dr. Miglis' opinions on HPV/POTS were found to be insufficient to satisfy Althen prong one. Id. at 2 (citing A.F. v. Sec'y of Health & Hum. Servs., No. 19-446V, 2023 WL 251948, at *22 (Fed. Cl. Spec. Mstr. Jan. 18, 2023)). The undersigned agreed with the prior rulings and found it would be difficult to find vaccine causation here. Id. at 2. Accordingly, the undersigned recommended that Petitioner's counsel confer with his client about these concerns before proceeding with further litigation. Id. Petitioner was ordered to file a motion to dismiss her case, or if she was unwilling to do so, file a motion for a ruling on the record. Id. at 3.

On July 11, 2023, Petitioner filed a joint status report advising Petitioner's wishes to proceed with a ruling on the record, "cognizant of the court's preliminary findings and conclusions." Pet. Joint Status Rept., filed July 11, 2023, at 1 (ECF No. 67). Petitioner anticipated the ruling would not substantively deviate from the opinions offered in the Rule 5 conference; "[h]owever, in order to preserve her ability to seek additional civil remedies and exhaust her administrative remedies, a judgment, not dismissal decision, is required under 42

[3] POTS is "a group of symptoms (not including hypotension) that sometimes occur when a person assumes an upright position, including tachycardia, tremulousness, lightheadedness, sweating, and hyperventilation; this is seen more often in women than in men, and the etiology is uncertain." Postural Orthostatic Tachycardia Syndrome, Dorland's Med. Dictionary Online, https://www.dorlandsonline.com/dorland/definition?id=111236 (last visited June 13, 2024).

U.S.C. § 300aa-21(a)(2)." Id. at 1. The parties were still deciding whether they wanted to file any supplemental expert reports given the desired course of action. Id. at 1-2. Petitioner proposed filing another joint status report setting forth deadlines for any supplemental expert reports and a briefing schedule for a motion for ruling on the record. Id. at 2. On July 25, 2023, Petitioner filed a joint status report proposing a ruling on the record briefing schedule. Pet. Joint Status Rept., filed July 25, 2023 (ECF No. 69). The parties did not indicate additional expert reports would be filed. Id.

Petitioner filed a motion for a ruling on the record on September 8, 2023. Pet. Motion for Ruling on the Record ("Pet. Mot."), filed Sept. 8, 2023 (ECF No. 73). Respondent filed his response on October 13, 2023. Resp. Response to Pet. Mot. ("Resp. Response"), filed Oct. 13, 2023 (ECF No. 74). Petitioner filed a reply on November 2, 2023. Pet. Reply to Resp. Response, filed Nov. 2, 2023 (ECF No. 79).

This matter is now ripe for adjudication.

II. PARTIES' CONTENTIONS

Petitioner and Respondent essentially desire the same outcome, a ruling on the record to resolve entitlement to compensation. See Pet. Reply at 1.

Petitioner requests an expedited ruling consistent with the Rule 5 order. Pet. Mot. at 8. In the Rule 5 order, the undersigned agreed it would be unlikely that Petitioner would succeed on entitlement. Rule 5 Order at 2. "Petitioner accepts the reality that the court's conclusion in its Rule 5 [o]rder is unlikely to change and entitlement will be rejected or denied." Pet. Mot. at 9. Still, Petitioner believes the best course of action to satisfy Petitioner's exhaustion requirements is to seek a ruling on the record. Id. at 7. Petitioner anticipates this ruling will not substantially deviate from the Rule 5 order and intends to reject such judgment to exhaust her remedies through the Vaccine Program and transfer her matter to a pending multi-district litigation regarding Gardasil and alleged injuries related to the vaccine. Id. at 8; Pet. Reply at 1.

Respondent argues Petitioner failed to establish she has POTS and/or mast cell activation syndrome ("MCAS").[4] Resp. Brief at 20-23. Respondent also believes Petitioner failed to satisfy all three Althen prongs. Id. at 23-28.

In her reply brief, Petitioner first states that the medical records include a conclusive diagnosis of POTS and "[t]here is no need for further extensive analysis of Petitioner's POTS diagnosis, as such a diagnosis was not questioned in the court's Rule 5 [o]rder." Pet. Reply at 2-3. Petitioner then clarifies that she does not seek a ruling "based on the premise that the record has shown Petitioner was entitled to compensation by satisfying the elements set forth in

[4] MCAS "is a condition of inappropriate release of histamine and other inflammatory mediators from circulating mast cells." Pet. ex. 20 at 3 (citing Pet. Ex. 24 at 1 (Peter Valent et al., Proposed Diagnostic Algorithm for Patients with Suspected Mast Cell Activation Syndrome, 7 J. Allergy Clinical Immunology 1125 (2019)).

Althen." Id. at 2. "Petitioner simply seeks an order from this court consistent with its Rule 5 [o]rder denying entitlement." Id. at 3.

III. FACTUAL HISTORY

A. Summary of Relevant Medical Records[5]

Prior to the vaccination at issue, Petitioner had a medical history of anxiety and migraines, and previously had a syncopal episode after receiving varicella and hepatitis A immunizations when she was eight years old. Pet. Ex. 5 at 223; Pet. Ex. 10 at 16, 18; Pet. Ex. 13 at 1692-93.

On December 28, 2017, Petitioner presented to her primary care provider ("PCP"), Dr. Brandon Ross, with a headache, nausea, sore throat, fever, chills, myalgia, fatigue, and loose stools for the past two to three days. Pet. Ex. 5 at 198. Her upper extremity joints were tender to palpation on examination. Id. at 199. Flu and rapid streptococcal pharyngitis ("strep")[6] tests were negative. Id. Dr. Ross recommended supportive care with ibuprofen, Dayquil, and Nyquil. Id. Petitioner was administered flu and meningococcal conjugate vaccinations that day as she did not have a fever and her vaccinations were overdue. Id.

Petitioner returned to Dr. Ross on February 1, 2018, with headaches, sore throat, sinus congestion, stomachache, nausea, body aches, and feeling warm for two days. Pet. Ex. 5 at 195. A rapid strep test was negative. Id. at 196. Dr. Ross diagnosed Petitioner with acute laryngopharyngitis, "likely viral in origin or exacerbated by allergies." Id. He recommended nasal saline rinses and Tylenol or Motrin as needed. Id. On this date, at 17 years old, Petitioner received the subject HPV vaccination in her right arm. Id.

Three days later, on February 4, 2018, Petitioner presented to the emergency department ("ED") at Skyridge Medical Center ("Skyridge") complaining of sore throat, neck swelling, dizziness, myalgia, dry cough, and a rash that had started on her feet and ascended to her legs. Pet. Ex. 10 at 35. Examination revealed bilateral pharyngeal erythema, cervical lymphadenopathy, and a maculopapular rash on both feet. Id. Dr. Adam Barkin suspected that

[5] This abbreviated summary is largely taken from Respondent's brief; however, only the most relevant medical records are included. For additional detailed medical records, see Resp. Response at 2-14.

[6] Strep is "an acute variety caused by infection with *Streptococcus pyogenes*; it occurs in epidemics and is usually spread by droplets or in air." Streptococcal Pharyngitis, Dorland's Med. Dictionary Online, https://www.dorlandsonline.com/dorland/definition?id=97469 (last visited June 13, 2024). "Characteristics include intense local hyperemia, sometimes with enlargement of cervical lymph nodes and a yellow exudate." Id.

Petitioner had mononucleosis infection ("mono")[7] but testing for mono and strep were negative. Id. at 38-39. Dr. Barkin prescribed an antibiotic and discharged Petitioner. Id. at 39.

Petitioner returned to the Skyridge ED on February 6, 2018, complaining of shortness of breath, dizziness, rash, back pain, fever, difficulty swallowing, sore throat, runny nose, diarrhea, and myalgias. Pet. Ex. 10 at 83. She reported her rash had gotten worse since she was last seen in the ED two days prior. Id. Laboratory testing showed an elevated white cell count and C-reactive protein level. Id. at 87. A chest X-ray was negative for pneumonia. Id. Petitioner was admitted for observation and further evaluation. Id. at 87-88.

The following day, February 7, 2018, Dr. Tom Anderson noted decreased swelling in Petitioner's tonsils following one dose of dexamethasone. Pet. Ex. 10 at 80. He also observed that Petitioner's rash had "essentially resolved in all of her body except her hands" and was no longer present on her legs or feet. Id. at 80-81. Testing for Epstein-Barr virus ("EBV"), cytomegalovirus ("CMV"), and mono were negative. Id. at 81, 135-36. Dr. Anderson discharged Petitioner with diagnoses of "a mono-like illness" and erythema multiforme minor rash. Id. at 81. He prescribed a five-day course of prednisone for throat swelling and recommended nasal spray for congestion and Benadryl for itching and rash. Id. One week later, on February 14, Petitioner returned to the Skyridge ED for severe abdominal pain. Id. at 204.

On February 26, 2018, Petitioner saw Dr. Ross for fever and swollen glands. Pet. Ex. 5 at 189. Rapid strep and flu tests were negative. Id. at 190. Dr. Ross felt Petitioner's symptoms were mono-like despite her previous negative test. Id. He was also concerned for an oncologic process, such as lymphoma, and referred Petitioner for further evaluation. Id.

The next day, on February 27, 2018, Petitioner presented to the ED at Anschulz Medical Campus ("Anschulz") reporting a history of fatigue, intermittent sore throat, and intermittent fever for one month. Pet. Ex. 2 at 2. It was noted she had been exposed to mono by classmates at school. Id. Petitioner was discharged with a diagnosis of viral pharyngitis and instructed to use Motrin. Id. at 4.

On March 1, 2018, Petitioner was evaluated by Bethany Thomas, CPNP-PC (certified pediatric nurse practitioner – primary care), in the pediatric otolaryngology clinic at Anschulz. Pet. Ex. 2 at 8-9. Ms. Thomas diagnosed Petitioner with adenotonsillar hypertrophy and chronic pharyngitis, "likely from recurrent viral illness as she ha[d] been sick for over a month." Id. at 8. Ms. Thomas prescribed a seven-day steroid taper. Id.

One week later, on March 8, 2018, Petitioner was seen in the ED at Anschulz for five weeks of sore throat, neck pain, spinal pain, and diffuse body aches. Pet. Ex. 2 at 12. A physical

[7] Mono is "an acute febrile illness of young adults, caused by the Epstein-Barr virus, a member of the Herpesviridae family; frequently spread by saliva transfer; characterized by fever, sore throat, enlargement of lymph nodes and spleen, and leukopenia that changes to lymphocytosis during the second week." Infectious Mononucleosis, Stedman's Med. Dictionary 1224 (28th ed. 2006).

examination revealed tenderness to palpation of all areas of the neck and enlarged tonsils but was otherwise normal. Id. A neck ultrasound showed cervical lymphadenitis.[8] Id. at 14. Blood work showed an elevated C-reactive protein level but was otherwise normal. Id. at 24. Viral cervical lymphadenitis was thought to be the most likely diagnosis. Id. at 15.

Two days later, on March 10, 2018, Petitioner returned to the Anschulz ED for abdominal pain, diarrhea, bloody stool, back pain, headaches, and dizziness. Pet. Ex. 2 at 28. Her mother was concerned that her symptoms were side effects of medication. Id. at 28-29. Blood work was ordered and showed elevated liver enzymes. Id. at 37-38. The next day, Petitioner returned to the ED for recurrence of rash and four-month history of multiple symptoms including intermittent rash, sore throat, abdominal pain, and bloody stool. Id. at 41. Upon examination, Petitioner's neck was tender to palpation, and she had enlarged tonsils and a diffuse maculopapular rash on her face and blanching red spots on her hands. Id. at 42-43. The ED physicians were concerned for EBV/CMV mono and requested an infectious disease consultation. Id. at 52. Petitioner was admitted for further evaluation. Id. at 40,49.

On March 13, 2018, Petitioner was examined by an infectious disease specialist, Dr. Samuel Dominguez. Pet. Ex. 2 at 59. Dr. Dominguez considered several possible diseases, including EBV, and ordered additional lab work. Id. Dr. Ross concluded that Petitioner's lab results favored an infectious process over an oncologic cause and recommended a rheumatology consult.[9] Id. at 65. On March 14, Dr. Dominguez noted that a repeat EBV test was positive, confirming a diagnosis of acute EBV infection. Id. at 86. He wrote, it was "not clear why it took that long for [the EBV titer] to become positive. She ha[d] [] been symptomatic for quite some time . . . . Her pharyngitis, lymphadenopathy, and tonsillar hypertrophy [were] also not unusual, but [were] on the more severe end of the spectrum of this disease." Id. He recommended a course of steroids. Id. Petitioner was discharged home on March 15, with a diagnosis of "[p]rolonged EBV [mono] course [with] significant painful cervical lymphadenopathy, rash, [and] sore throat." Id. at 47.

On March 26, 2018, Petitioner saw Dr. Ross with complaints of hip, leg, back, and eye pain, as well as nausea. Pet. Ex. 5 at 183. Dr. Ross observed that Petitioner had "experienced significant deconditioning over the course of her illness in the last month" and recommended stretching. Id. at 184

Petitioner presented to the Anschulz ED on April 1, 2018, with sharp abdominal pain that moved from the right lower quadrant to right upper quadrant of her abdomen. Pet. Ex. 2 at 112. An abdominal ultrasound was performed and showed enlargement of the liver and spleen. Id. at 118-19. Petitioner was discharged with diagnoses of EBV infection and abdominal pain. Id. at 118.

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[8] Lymphadenitis is "inflammation of one or more lymph nodes, usually caused by a primary focus of infection elsewhere in the body." Lymphadenitis, Dorland's Med. Dictionary Online, https://www.dorlandsonline.com/dorland/definition?id=28974 (last visited June 13, 2024).

[9] A rheumatology evaluation by Dr. Katharine Moore found "low suspicion for rheumatology etiology." Pet. Ex. 2 at 238.

At a follow-up with Dr. Ross on April 5, 2018, Petitioner's mother reported "researching Gardasil and found rashes just like [Petitioner's] and had a number of consequences similar to her like chronic fatigue and long lasting myalgias." Pet. Ex. 5 at 180. Dr. Ross referred Petitioner to infectious disease for her mono and for "questions about post-HPV vaccine syndrome." Id. at 181.

From April 9 to April 10, 2018, Petitioner was hospitalized at Anschulz for weight loss, abdominal pain, painful urination, headaches, and light sensitivity. Pet. Ex. 2 at 121. She reported that her symptoms started the day after she received an HPV vaccination. Id. at 122. Neurology was consulted and had no concerns for an acute neurologic process. Id. at 134. An infectious disease specialist concluded that Petitioner's symptoms were most consistent with post-viral syndrome, writing that Petitioner "[m]ay have had separate virus during illness in Feb[ruary] with rash and then developed EBV during recovery phase while on steroids which would explain previous EBV negative results and now positive EBV tests [two times]." Id. at 136. Petitioner was diagnosed with headache, depression, and weight loss. Id. at 133-34.

On April 24, 2018, Petitioner saw infectious disease specialist, Dr. Sarah Saporta-Keating, for ongoing symptoms, including headache, nausea, lethargy, body aches, joint pain, congestion, and dizziness. Pet. Ex. 2 at 187. Dr. Saporta-Keating wrote that Petitioner's "more persistent symptoms of fatigue, body aches, joint pains" were "likely secondary to her [mono]." Id. She thought Petitioner would benefit from a physician who specialized in chronic fatigue and post-infectious fatigue, and suggested Dr. David Kaplan in the adolescent medicine department. Id.

Petitioner saw Chelsey Stillman, PA-C (certified physician assistant), in the Anschulz neurology department on May 21, 2018. Pet. Ex. 2 at 222-26. Petitioner reported feeling very dizzy when moving from sitting to standing and sometimes having a rapid heart rate. Id. at 226. Petitioner further reported that she "[did not] get out of bed [un]til noon," was "too tired to exercise," and did not have an appetite as she was "always nauseous." Id. Ms. Stillman diagnosed Petitioner with POTS based on a "36 BPM change from sitting to standing"[10] and referred Petitioner to the adolescent medicine department. Id. at 222. Other diagnoses included chronic migraine, anxiety, and nausea. Id.

On June 5, 2018, Petitioner saw Dr. Kaplan, an adolescent medicine specialist at Anschulz. Pet. Ex. 2 at 247. He diagnosed Petitioner with POTS based on a ten-minute standing test, as well as anxiety and chronic headaches. Id. at 248. Petitioner remained under Dr. Kaplan's care for POTS. See Pet. Ex. 3 at 420, 434. Petitioner started physical therapy for POTS on June 12, 2018. Pet. Ex. 2 at 249.

On June 15, 2018, Petitioner was evaluated by Rupal Deitz, NP (nurse practitioner), in the allergy/immunology department at Anschulz for recurrent rashes and hives which were

[10] On June 18, 2018, Petitioner had a cardiology evaluation for POTS. Pet. Ex. 2 at 265. Petitioner did not report palpitations outside of a mild increase in heart rate when standing. Id. Dr. Kathryn Collins indicated no further cardiology follow-up was necessary. Id.

possibly secondary to EBV infection. Pet. Ex. 2 at 255. Petitioner's mother reported that Dr. Kaplan advised Petitioner to avoid the HPV vaccine "for now" and to consider getting a second dose of HPV vaccine before age 26. Id. at 256. Ms. Deitz wrote that she was "uncertain if [Petitioner] had a true adverse reaction due to compounding viral symptoms presented" but advised that, if Petitioner decided to get another HPV vaccine, her case should be re-evaluated by an allergist or immunologist first. Id. at 254.

Petitioner saw Dr. Fred Atkins in the allergy/immunology department at Anschulz on February 28, 2019. Pet. Ex. 3 at 240. Petitioner's mother reported that when Petitioner was one year old, she developed a rash which was thought to be chicken pox, "but may have had Henoch-Schonlein purpura given that the rash was purpuric and involved only her lower extremities. Recently, after receiving the HPV vaccine, she has had recurrent urticarial rashes, some of which appeared purpuric as well." Id. Dr. Atkins wrote that "the cause of [the rashes] [was] unclear although [mono] was diagnosed." Id.

Petitioner continued to see multiple providers overtime and a POTS diagnosis was consistent. See, e.g., Pet. Ex. 3 at 7 (noting "[o]ngoing autonomic dysfunction/POTS and [gastrointestinal] symptoms").

B. Petitioner's Affidavit

Prior to the vaccination at issue, Petitioner averred she did not experience POTS or POTS-like symptoms. Pet. Ex. 4 at ¶ 16. "Shortly after [her] vaccination," Petitioner began to develop "symptoms such as fatigue, sore throat, skin rashes and hives, and fevers." Id. at ¶ 7. Twenty-six days after the vaccination, she went to the ED for her ongoing symptoms. Id. at ¶ 8. She had been admitted to the hospital several times for her symptoms and in spring of 2018, she was diagnosed with POTS. Id. at ¶¶ 9-10. Petitioner continues to have POTS symptoms which she relates to her HPV vaccination. Id. at ¶ 14.

C. Expert Reports[11]

1. Petitioner's Expert, Dr. Mitchell G. Miglis[12]

Dr. Miglis is a board-certified neurologist. Pet. Ex. 20 at 1. During his time in practice, Dr. Miglis estimated that he has managed "over three hundred unique patients with POTS." Id. Dr. Miglis is currently an Associate Professor in the Neurology Department at Stanford University and specializes in disorders of the autonomic nervous system. Id. He also conducts clinical research on POTS and other autonomic disorders. Id.

[11] While the undersigned has fully reviewed the expert reports, she does not discuss them in depth here.

[12] Dr. Miglis provided two expert reports. Pet. Exs. 20, 52.

Dr. Miglis opined there is no single established etiology for POTS, although "the role of autoimmunity has garnered increased attention in recent years." Pet. Ex. 20 at 4. He noted "several publications that have described autoantibodies to G-protein-coupled receptors (GPCRs) in patients with POTS, supporting the growing evidence that the trigger for many patients with POTS may very well be autoimmune in nature." Id. Dr. Miglis suggested several mechanisms of vaccine-induced injures but acknowledged that POTS and other adverse reactions to Gardasil are still being explored. Id. at 9. Dr. Miglis proposed molecular mimicry between components of Gardasil and components of the adrenergic receptors on autonomic nerves and mast cells as the theory of causation here. Id. at 16.

He opined Petitioner's initial allergic symptoms developed within 24 hours of vaccination and first experienced "disabling orthostatic intolerance" two weeks after vaccination. Pet. Ex. 20 at 16. He opined the "time course of several weeks to onset of initial symptoms with gradual progression over several months is a reasonable time frame for an adaptive autoimmune response." Id.

Petitioner concedes that Dr. Miglis' theories have been rejected in prior reasoned vaccine decisions. Pet. Mot. at 4 n.1.

2. Respondent's Expert, Dr. Andrew MacGinnitie[13]

Dr. MacGinnitie is board certified in allergy/immunology and pediatrics. Resp. Ex. A at 2. He currently is an Attending Physician and the Clinical Chief for the Division of Immunology at Boston Children's Hospital as well as an Associate Professor of Pediatrics at Harvard Medical School. Id. at 1. He "maintain[s] an active clinical practice seeing more than 1600 patients annually and ha[s] extensive experience in caring for children and adults with a variety of immunologic diseases including reactions to vaccines." Id. at 2. He routinely evaluates patients for MCAS; however, he does not routinely care for patients with POTS, except if they have concurrent allergic or immunologic issues. Id.

Dr. MacGinnitie opined Petitioner did not have MCAS, there is little evidence that POTS or MCAS are autoimmune diseases, and Petitioner's onset of symptoms (dizziness the day of vaccination) was too rapid after vaccination to be plausible for an adaptive autoimmune process. Resp. Ex. A at 8. He also opined there is no molecular mimicry between Gardasil and human proteins and no association with HPV vaccination and POTS. Id. at 13, 15.

He noted that Petitioner's treating providers did not believe her symptoms were triggered by the vaccination. Resp. Ex. A at 14. Dr. MacGinnitie opined a combination of anxiety and deconditioning were more likely the causes of Petitioner's symptoms. Id.

[13] Dr. MacGinnitie provided one expert report. Resp. Ex. A.

3. Respondent's Expert, Brian Olshansky[14]

Dr. Olshansky is board certified in clinical cardiac electrophysiology, cardiology, and internal medicine, and has a certified subspecialty in autonomic disorders. Resp. Ex. C at 1. He is currently a Professor Emeritus at the University of Iowa and a practicing cardiac electrophysiologist. Id. In his electrophysiology clinic, he routinely sees patients with autonomic disorders or suspected autonomic disorders, including POTS. Id. at 1-2.

Dr. Olshansky opined the cause of POTS is not established. Resp. Ex. C at 13-14. He cited literature to show that there is no data to support a causal relationship between HPV vaccination and POTS. Id. at 14, 22.

He opined Petitioner had symptoms that predated her vaccination and some of her post-vaccination symptoms were not consistent with POTS. Resp. Ex. C at 14-16. Dr. Olshansky opined that even if Petitioner had POTS, it was most likely due to severe and chronic viral infections, including her well-documented history of mono and EBV infection. Id. at 18. He stated this would better explain the symptoms that occurred after vaccination even those that were inconsistent with POTS. Id.

IV. DISCUSSION

A. Standards for Adjudication

The Vaccine Act was established to compensate vaccine-related injuries and deaths. § 10(a). "Congress designed the Vaccine Program to supplement the state law civil tort system as a simple, fair and expeditious means for compensating vaccine-related injured persons. The Program was established to award 'vaccine-injured persons quickly, easily, and with certainty and generosity.'" Rooks v. Sec'y of Health & Hum. Servs., 35 Fed. Cl. 1, 7 (1996) (quoting H.R. Rep. No. 908 at 3, reprinted in 1986 U.S.C.C.A.N. at 6287, 6344).

Petitioner's burden of proof is by a preponderance of the evidence. § 13(a)(1). The preponderance standard requires a petitioner to demonstrate that it is more likely than not that the vaccine at issue caused the injury. Moberly v. Sec'y of Health & Hum. Servs., 592 F.3d 1315, 1322 n.2 (Fed. Cir. 2010).

To receive compensation through the Program, Petitioner must prove either (1) that she suffered a "Table Injury"—i.e., an injury listed on the Vaccine Injury Table—corresponding to a vaccine that she received, or (2) that she suffered an injury that was actually caused by a vaccination. See §§ 11(c)(1), 13(a)(1)(A); Capizzano v. Sec'y of Health & Hum. Servs., 440 F.3d 1317, 1319-20 (Fed. Cir. 2006). Petitioner must show that the vaccine was "not only a but-for cause of the injury but also a substantial factor in bringing about the injury." Moberly, 592 F.3d at 1321 (quoting Shyface v. Sec'y of Health & Hum. Servs., 165 F.3d 1344, 1352-53 (Fed. Cir. 1999)).

[14] Dr. Olshansky provided one expert report. Resp. Ex. C.

Because Petitioner does not allege she suffered a Table Injury, she must prove a vaccine she received actually caused her injury. To do so, Petitioner must establish, by preponderant evidence: "(1) a medical theory causally connecting the vaccination and the injury; (2) a logical sequence of cause and effect showing that the vaccination was the reason for the injury; and (3) a showing of a proximate temporal relationship between vaccination and injury." Althen, 418 F.3d at 1278.

B. Analysis

There are other similar Vaccine Program cases involving HPV and POTS. Generally, special masters have denied entitlement in those cases. The undersigned has issued a reasoned decision in such case, but her denial of entitlement was based on petitioner's failure to prove a diagnosis of POTS. See Ingber v. Sec'y of Health & Hum. Servs., No. 18-1061V, 2019 WL 7818779, at *4 (Fed. Cl. Spec. Mstr. Dec. 30, 2019). The undersigned finds the medical records support a diagnosis of POTS here. No medical opinion was offered to support petitioner's causation allegations in Ingber. Id. at *4-5.

However, there is a body of case law where medical opinions were offered but special masters still found no basis for entitlement. For example, in the most recent reasoned decision, the chief special master denied entitlement in an HPV/POTS case and explained that "no persuasive reasoned [Vaccine] Program decisions" have been able to draw a causal association between the HPV vaccine and POTS, or any autonomic dysfunction. A.F., 2023 WL 251948, at *22 (emphasis omitted); see e.g., America v. Sec'y of Health & Hum. Servs., No. 17-542V, 2022 WL 278151, at *27 (Fed. Cl. Spec. Mstr. Jan. 4, 2022) (ruling against petitioner's argument that the HPV vaccine can interfere with the nervous system sufficient to cause POTS); Johnson v. Sec'y of Health & Hum. Servs., No. 14-254V, 2018 WL 2051760, at *24-25 (Fed. Cl. Spec. Mstr. Mar. 23, 2018) (denying entitlement and noting that medical literature failed to demonstrate that POTS is more often than not autoimmune); Combs v. Sec'y of Health & Hum. Servs., No. 14-878V, 2018 WL 1581672, at * 1 (Fed. Cl. Spec. Mstr. Feb. 15, 2018) ("Petitioner's causation theory—that the HPV vaccine could damage the autonomic nervous system—was scientifically unreliable and unpersuasive . . . ."); McKown v. Sec'y of Health & Hum. Servs., No. 15-1451V, 2019 WL 4072113, at *50 (Fed. Cl. Spec. Mstr. July 15, 2019) (stating that molecular mimicry was not reliably invoked to explain vaccine association with syncopal symptoms); Drummond v. Sec'y of Health & Hum. Servs., No. 16-702V, 2023 WL 3035072, at *28-32 (Fed. Cl. Apr. 21, 2023) (denying compensation for HPV/POTS case based on a theory of molecular mimicry); Hughes v. Sec'y of Health & Hum. Servs., No. 16-930V, 2021 WL 839092, at *30 (Fed. Cl. Spec. Mstr. Jan. 4, 2021) (same); C.F. v. Sec'y of Health & Hum. Servs., No. 15-731V, 2023 WL 2198809, at *34 (Fed. Cl. Spec. Mstr. Jan. 20, 2023) (denying entitlement and noting it was a not a close case and that special masters "have repeatedly rejected claims that the HPV vaccine can cause POTS and/or autonomic dysfunction"). The undersigned generally agrees with her colleagues' reasoning and analyses in these cases.

Even in A.F., where the petitioner offered additional, recently published medical or scientific literature regarding POTS and autoimmunity/autoantibody association, the chief

special master still found "its connection with the HPV vaccine has not been preponderantly established." A.F., 2023 WL 251948, at *23-24; see also Hughes, 2021 WL 839092, at *30-31.

Additionally, Dr. Miglis has offered expert opinions for petitioners in other POTS cases suggesting the same or similar theory that is offered here—molecular mimicry due to components of the HPV vaccine and components of the adrenergic receptors on autonomic nerves. See A.F., 2023 WL 251948, at *4; Balasco v. Sec'y of Health & Hum. Servs., No. 17-215V, 2020 WL 1240917, at *12 (Fed. Cl. Spec. Mstr. Feb. 14, 2020). Those cases found Dr. Miglis' opinions insufficient to satisfy Althen prong one.

Given that Dr. Miglis' same opinions on HPV/POTS have recently been insufficient to satisfy Althen prong one, that no claim alleging that the HPV vaccine can cause POTS has succeeded in the Vaccine Program, and the undersigned's agreement with the reasoning and analyses of her colleagues, the undersigned finds Petitioner has failed to offer a sound and reliable medical theory in support of her claim. Thus, the undersigned finds Petitioner has failed to provide preponderant evidence with respect to the first Althen prong.

Since Petitioner failed to prove Althen prong one, it follows that she cannot prove Althen prongs two or three. See K.L. v. Sec'y of Health & Hum. Servs., 134 Fed. Cl. 579, 592, 606 (2017) (noting Petitioner must satisfy all three Althen prongs to prevail on entitlement and because Petitioner failed to carry her burden under Althen prong one, it was unnecessary to discuss Petitioner's showings under the other Althen prongs) (citing Althen 418 F.3d at 1278); Phelan v. Sec'y of Health & Hum. Servs., No. 18-1366V, 2024 WL 1174097, at *34 (Fed. Cl. Spec. Mstr. Feb. 20, 2024) ("Because Althen prong three is dependent on the medical theory required by Althen prong one, Petitioner's inability to meet her burden [under Althen prong one] effectively precludes her from being able to meet [her] burden under the third Althen prong.").

V. CONCLUSION

For the reasons discussed above, the undersigned finds that Petitioner has failed to provide preponderant evidence of causation, and therefore, the Petition must be dismissed. In the absence of a timely filed motion for review pursuant to Vaccine Rule 23, the Clerk of Court **SHALL ENTER JUDGMENT** in accordance with this Decision.

IT IS SO ORDERED.

s/Nora Beth Dorsey
Nora Beth Dorsey
Special Master